IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Docket No.: ATM-2244

Applicant

Wilfried JUD et al.

Serial No.

09/505,713

Examiner: Monique R. Jackson

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Art Unit: 1773

Title

STERILIZABLE COMPOSITE FILM.

DECLARATION

Commissioner for Patents Washington, D.C. 20231

Dear Sir:

Hans P. Breitler declares and states:

- (1) He is the first-listed joint inventor in U.S. Patent No. 5,589,275, issued on December 31, 1996.
- (2) He and the other two joint inventors were employed by a sister company of Alusuisse-Lonza Services AG, and assigned their invention and U.S. Application Serial No. 318,643, from which U.S. Patent No. 5,589,275 issued, to Alusuisse-Lonza Services AG. Also, Alusuisse-Lonza Services AG and Alusuisse Technology & Management Ltd. are the same Swiss corporation; there has been a change of corporate name. (The corporate name of Alusuisse Technology & Management Ltd. has recently been changed to Alcan Technology & Management Ltd.)
- (3) U.S. Patent No. 5,589,275 involves a composite material for the base part of blister packs for use in freeze drying applications for foodstuffs and pharmaceuticals. The basic structure of the composite material is a metal layer (foil) with a plastic layer on each side thereof. The plastic layers contain or comprise polyamide-based thermoplastics.

 U.S. Patent No. 5,589,275 does not teach or suggest the inclusion of a polypropylene layer

(or other sealing/sealable layer) between either or both of the plastic layers and the metal layer. The joint inventors of the composite material of U.S. Patent No. 5,589,275 did not disclose or contemplate that their involved invention included a polypropylene layer (or other sealing/sealable layer) between either or both of the plastic layers and the metal layer.

(4) The text in lines 9 to 45 of column 4 of U.S. Patent No. 5,589,275 only refers to the optional presence of a sealing/sealable layer on the outside surface of either or both of the plastic layers in the composite material itself, namely:

(3a)	sealing layer	_
(2a)	plastic layer	_
(1)	metal foil	_
(2b)	plastic layer	_
(3b)	sealing laver	_

Such text in column 4 does not refer, as such, to the presence of a sealing layer on one or both sides of either or both plastic layers separate from the basic structure of the composite. Or, in other words, such column 4 text does *not* disclose the following structures, for example:

not:	sealing layer
	plastic layer
	sealing layer
	metal foil
	sealing layer
	plastic layer
	sealing layer
and not:	plastic layer
	metal foil
	sealing layer
	plastic layer
	sealing layer

and not:

plastic layer

metal foil

sealing layer

plastic layer

(5) There is no teaching of a sealing layer between either or both plastic layers of the metal layer (the basic composite material structure) in the text in lines 9 to 45 of column 4 of U.S. Patent No. 5,589,275, which reads as follows:

"The plastic layers on both sides of the metal layer, in particular the polyamide-based thermoplastics may additionally, and independent of each other, be provided with an outer lying sealable layer and/or a barrier layer of thermoplastics."

"The composite according to the invention may also feature a sealing layer or sealable layer on one or both sides."

"The composite material according to the present invention forms a composite containing plastic film that, in order to extend the range of properties, may be coated with one or more layers of material such as e.g. plastic films."

"Sealable layers are e.g. sealable films deposited e.g. via adhesives that contain or are free of solvents, or water-based adhesive systems, applied by extrusion lamination or lamination coating. Sealable films may contain or consist of e.g. LLDPE, LDPE, MDPE, HDPE, polypropylenes, polyethylene-terephthalate or polyolefin-based isomers. Ionomers or ionomer-containing polymers with typical properties of ionomers may be thermoplastic copolymers of olefin with carboxyl-containing monomers, a part of which are present as free carboxyl groups and the remainder bonded to metal cations so that some transverse cross-linking is achieved. Polyethylene-based ionomers are known under the trade name Surlyn.

Sealable films may be 6 to 100 μ m thick. Furthermore, one or more layers e.g. 1 to 10 μ m thick, of a sealing coating or hot-sealing coating for example, may be deposited on the plastic film composite."

"A single or double-sided sealable composite is obtained by single or double-sided coextrusion of the plastic layers with e.g. a polypropylene/polyethylene copolymer."

"In that connection it is useful for the plastic layers to contain or comprise of a polyamide-based thermoplastic and at least one a polyamide-based thermoplastic to feature a sealing layer on at least one side i.e. each layer of polyamide-based thermoplastic may be covered with a sealable layer on one or both sides, independent of the other layers."

All references to sealing layers in such text are exclusively to sealing layers, located on the outer surfaces of the composite material, i.e., on the outer surface of the plastic layers of the composite material.

(6) The text in lines 9 to 13 of column 4 of U.S. Patent No. 5,589,275 reads as follows:

"The plastic layers on both sides of the metal layer, in particular the polyamide-based thermoplastics may additionally, and independent of each other, be provided with an outer lying sealable layer and/or a barrier layer of thermoplastics."

Such text is not discussing the plastic layers by themselves but only as components in the structure of the basic composite material. The use of the phrase "outer lying sealable layer" refers only to the outside surfaces of the basic composite material (i.e., the outside

surface of each of the plastic layers). The words "outer lying" refer only to the side of each of the plastic layers away from the metal foil.

The phrase "on outer lying sealable layer and/or a barrier layer" restricts the sealable layer to the outside surface of the plastic layers in the composite material. The term "outer lying" does not modify the barrier layer.

When the inventors meant that a substance or layer could be located between a plastic layer and the metal layer, the text clearly says or indicates so. Column 4, lines 46 to 61, of U.S. Patent No. 5,589,275 states:

"Beside the metal foil, at one additional layer may be provided as a barrier layer *** *** Barrier layers are situated for example between the metal layer and the polyamide layer or layers; the barrier layers are preferably situated on the polyamide layer on the opposite side facing the metal layer. Foreseen in particular is a barrier layer on one side of the metal layer only, lying on the polyamide layer."

The above quotation recites that the barrier layer can be between one of the plastic layers and the metal foil. The term "outer lying" does not modify "a barrier layer", but restricts the location of the "sealable layer" to the outside surface of the plastic layer away from the metal foil.

(7) The text in lines 36 to 45 of column 4 of U.S. Patent No. 5,589,275 reads as follows:

"A single or double-sided sealable composite is obtained by single or double sided coextrusion of the plastic layers with e.g. a polypropylene/polyethylene copolymer."

"In that connection it is useful for the plastic layers to contain or comprise of a polyamide based thermoplastic and at least one a polyamide based thermoplastic to

feature a sealing layer on at least one side, i.e., each layer of polyamide based thermoplastic may be covered with a sealable layer on one or both sides, independent of the other layers."

Such text only discusses the basic composite material, placement of a sealable layer on the outer or outside surface of at least one of the plastic layers in the basic composite method. Such text does not refer to one or both of sides of a plastic layer (in the composite material) having a sealable layer thereon — such is not part of the invention described in U.S. Patent No. 5,589,275.

The following information further shows that, in U.S. Patent No. 5,589,275, no sealing layer is arranged between the metal foil and the polyamide layer. The single purpose of the sealing layer of U.S. patent No. 5,589,275 is to secure a lid on top of the base part of a packaging formed by the composite of said patent. Therefore, the sealing layer always forms the outmost layer of a base part made from the composite and the sealing layer has a free surface. Depending on the kind of plastic film, the sealing layer is a necessity, otherwise it would not be possible to safely fix or seal the lid to the base part of a packaging. In other words, the sealing layer has to be exposed to the outside to meet the lid. This information is supported in U.S. Patent No. 5,589,275, at column 7, lines 44 to 47, column 7, lines 62 to 67 (another sealing layer having a free surface at the lid to meet the base part is mentioned), and column 8, lines 19 to 21.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of the United

States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: <u>04/04/02</u>

Hans P. Breitler